Statement
of the

American Pharmacists Association

OxyContin and Beyond: Examining the Role of FDA and DEA in Regulating Prescription Painkillers

Submitted to the House Government Reform Committee Subcommittee on Regulatory Affairs

September 13, 2005
Boston, Massachusetts

American Pharmacists Association
2215 Constitution Avenue, N.W.
Washington, DC 20037-2985

(202) 628-4410
http://www.APhAnet.org

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The American Pharmacists Association (APhA) welcomes the opportunity to present the pharmacist's perspective on the role of the Food and Drug Administration (FDA) and the Drug Enforcement Agency (DEA) in regulating prescription pain medications. As the medication experts on the health care team, and the health professionals dedicated to partnering with patients to improve medication use, we appreciate the opportunity to discuss the importance of striking a balance between providing effective health care and preventing prescription drug abuse and diversion. APhA, founded in 1852 as the American Pharmaceutical Association, represents more than 53,000 pharmacist practitioners, pharmaceutical scientists, student pharmacists, pharmacy technicians, and others interested in advancing the profession

APhA agrees that the diversion and abuse of prescription medications is a significant public health problem. Everyday, pharmacists work collaboratively with prescribers and other health care providers to prevent the diversion of prescription medications and to identify incidents of abuse or addiction. Because activities of the FDA and DEA impact the ability of pharmacists to provide patients access to prescription pain medications and therefore appropriate pain care, APhA and its members are committed to working with Congress, the FDA, the DEA, other health care providers, and patients to find the appropriate balance between appropriate medication use and measures to curb the abuse and diversion of prescription drugs. However, APhA is very concerned with recent proposals to circumvent the FDA's authority to determine which drugs should be in the market and recent DEA activities that may result in a 'chilling effect' on effective pain care — creating barriers to reign in 'bad actors' should not limit access to legitimate medications.

FDA: Step One

What drugs should be available in the market are critical decisions that impact the workings of our health care system. These decisions are best conducted by the FDA. The FDA reviews data provided by drug manufacturers to determine whether a drug may be marketed safely. APhA opposes efforts to circumvent this review process, such as through the legislative process. Using the legislative process to set clinical policy circumvents the thoughtful, scientific-based dialogue that supports the Food and Drug Administration's decisions. What may appear to be a simple decision to a legislator is to a clinician an intrusion on their ability to provide their patients necessary and appropriate care.

APhA is particularly concerned with legislative efforts to remove specific drugs, such as pain medications, from the market. Opiate analgesics like OxyContin® are a valuable tool in the management of pain. Opiate analgesics have significant therapeutic value for the millions of patients who suffer from chronic pain due to disease, injury, or surgery – pain that other medications will not alleviate. The legislative process is an inappropriate way to remove a drug from the market; legislative proposals to remove FDA-approved pain medications from the market ignore the value these products provide to patients who suffer from pain. APhA supports continued use of the FDA as the Agency that should make these types of decisions.

DEA: Step Two

Once a drug is approved for marketing by the FDA, the next step is determining whether restrictions should be placed on the access to the drug because of the drug's level of potential for abuse and dependency. The Drug Enforcement Administration (DEA) plays a role in managing the accessibility of addictive drugs through enforcing the U.S. controlled substances laws and regulations and supporting programs aimed at reducing the availability of illicit controlled substances on the domestic and international markets.

While limiting illicit trafficking of prescription medications is very important, we must provide a balanced approach to enforcement efforts. It is imperative that we balance the need to regulate the 'bad actors' with the need to address the health care needs of patients who have legitimate medical conditions that require access to prescription pain medications. Without an appropriate balance of law enforcement and health care, patients suffer unnecessarily.

Pharmacists: Step Three

Determining whether a drug is available on the market and determining how tightly to control these products are just the first steps of providing patients access to appropriate medication therapy. The final decision of whether an individual patient should receive a specific medication should be a decision that involves the patient, the prescriber, and the pharmacist. Involvement of pharmacists is an appropriate and effective way of mitigating abuse and diversion.

Pharmacists work with patients to help them use their medications appropriately. Prescription drug abuse is one type of medication misuse that pharmacists try to prevent. Working collaboratively with prescribers and other health care providers, pharmacists prevent the diversion of prescription medications and identify incidents of abuse or dependency. As part of this process, pharmacists assess the appropriateness of every prescription order they review or dispense. Every day, pharmacists assess the validity of prescriptions, watching for errors in the content or format of the communications. They also watch for individuals who attempt to fill fraudulent prescriptions, visit multiple prescribers, or present prescriptions for unusually large quantities of medication. However, it is not always easy to determine if a prescription is legitimate – no simple algorithm determines appropriate use. And importantly, pharmacists cannot view every patient as a potential drug abuser without compromising their responsibilities as a health care professional.

Chilling Effect on Care

Although APhA agrees that some action is necessary to address the diversion and abuse of prescription medications, we know that some well-intentioned interventions can actually create new problems. Every effort to prevent diversion and abuse has the potential to diminish appropriate prescribing and dispensing exponentially. Any additional stigma attached to the drugs will have a significant impact on health care providers' willingness to prescribe and dispense appropriate pain medication and patients' interest in using the medications. While decreasing the number of controlled substance prescriptions written and dispensed may be seen as a way to decrease the opportunity for diversion and abuse, it is not an appropriate solution. Law enforcement efforts to reduce abuse and diversion can negatively impact care to thousands of patients living in pain who could be helped by appropriate use of controlled substances.

A recent example of the DEA going one step too far is its recent withdrawal of support for the pain management guidance "Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel" (FAQ) and its release of an interim policy statement on the dispensing of controlled substances for the treatment of

pain. APhA is troubled that these actions signal a change in the Agency's direction. The Agency appears to be shifting away from striking a balance between appropriate pain management and strategies to reduce diversion and abuse, to an increased emphasis on investigation and prosecution.

Specifically, the Agency's interim policy statement contains a list of nine factors that the DEA believes may indicate diversion or abuse of controlled substances. While several of the factors may help the Agency distinguish between legitimate medical use and diversion or abuse, a pattern of diversion or abuse will only be evident if multiple factors are considered in concert with one another, and the Agency examines the unique situation of the prescriber and patients involved. The FAQ implies that the Agency may launch an investigation and/or prosecution of a health care professional because the individual appears to meet one of the factors listed. According to the DEA, just one of these factors – the number of patients, the quantity of controlled substances prescribed, or the length of therapy – may indicate that a health care professional is involved in diversion or abuse. APhA strongly disagrees with this conclusion.

The number of patients prescribed controlled substances, the quantity prescribed to each patient, and the duration of the drug therapy are not good indicators of diversion and abuse when considered by themselves. There are a number of legitimate medical reasons why a prescriber might prescribe controlled substances to a large number of his/her patients, prescribe significant quantities, and keep a patient on therapy for long periods of time. Physicians who specialize in pain management, because of the very nature of their practice, may have a large number of patients who require opiate analgesics to manage their pain. Patients who grow tolerant to a medication or experience break-through pain may need increasingly larger quantities of the drug to manage their pain. And patients who have chronic pain due to disease, illness, or surgery may need to remain on the drug therapy for extended periods of time.

APhA is also troubled by how the DEA's interim policy statement addresses the preparation of multiple prescriptions. The DEA takes issue with a statement from the Prescription Pain Medications FAQ which states, "Schedule II prescriptions may not be refilled; however, a physician may prepare multiple prescriptions on the same day with instructions to fill on different days."[1] According to the Agency's most recent interpretation of the Controlled Substances Act (CSA), however, the second half of the statement, "a physician may prepare multiple prescriptions on the same day with instructions to fill on different days," is incorrect. The DEA argues that this practice is tantamount to writing a prescription authorizing refills of a Schedule II controlled substance, which is prohibited.

APhA does not dispute the fact that prescriptions for Schedule II controlled substances may not be refilled. This is an established and settled matter of statutory, regulatory, and case law. However, we disagree that the scenario in question here – the preparation of multiple prescriptions on the same day with instructions to fill on different days – is equivalent to the authorization of refills. In this case, each prescription is prepared on a separate prescription blank or form and each prescription bears the date the prescription was issued and signed, the name and address of the patient, the drug name, strength, dosage form, quantity prescribed, and directions for use, and the name, address, and DEA registration number of the prescriber. Each prescription

[1] Prescription Pain Medications: Frequently Asked Questions and Answers for Health Care Professionals, and Law Enforcement Personnel. Supported by the Drug Enforcement Administration, Last Acts Partnership, and Pain & Policy Studies Group of the University of Wisconsin. 2004; pg. 39.

meets the requirements for a controlled substance prescription under the CSA.[2] Each prescription stands as a separate, new prescription for the medication prescribed.

The preparation of multiple prescriptions on the same day with instructions to fill on different days, is also a long-standing accepted medical practice – a practice the DEA itself has recognized and encouraged several times in the past. In a 1995 letter from the DEA to MEIJER, Inc., the Agency described a situation in which a prescriber "signs and dates as many as six prescriptions on the day of issuance…the prescriptions are noted that the pharmacist is not to dispense the prescription for 30, 60, 90 or 120 days." The letter continues to state that "there appears to be no violation of current federal laws or regulations in the prescribing manner you have described."[3] The letter clearly illustrates that the Agency had no objection to this practice, and that the issuance of multiple prescriptions with instructions to fill on future dates is not in violation of the CSA or subsequent regulations. The DEA has reiterated this stance on several other occasions including official Agency correspondence dated January 31, 2003. In that letter, the DEA clearly stated its approval of the practice:

> The DEA regulations do not prohibit a practitioner from issuing more than one prescription at a time. If, in keeping with the practitioner's professional medical judgment, multiple prescriptions are issued at one time, each must bear the actual date that the prescriptions were issued and signed as well as the directions for dispensing. For example, if three prescriptions, each for a 30-day supply, are issued on January 9, 2003, each prescription must be dated January 9, 2003. In addition, the prescriptions to be filled at later dates must include directions for the dispensing pharmacist such as, "do not dispense before February 9, 2003." Although Title 21 of the Code of Federal Regulations, Section 1306.12 (21 CFR 1306.12) prohibits the refilling of a prescription for a Schedule II controlled substance, the DEA does not consider multiple prescriptions in the scenario outlined above as refills, and has authorized this practice provided that it is not in violation of the laws of the state in which the practitioner is licensed.[4]

The Agency's decision to reverse its position on this practice in the interim policy statement is confusing, inappropriate, and jeopardizes patient care. Prescribers have been issuing multiple prescriptions in this manner for years with the Agency's approval. There is no new law or regulation that serves as the basis of the Agency's new position. Similar to the Agency's change in position regarding the factors that may indicate diversion or abuse, the DEA's sudden change in position regarding multiple prescriptions will confuse health care professionals and dramatically affect patient care. This confusion will be compounded by the fact that many state boards of medicine and pharmacy continue to endorse the practice.

It is important that prescribers continue to be allowed to issue multiple prescriptions in this manner. Prescribers issue multiple prescriptions at one time to help improve patient compliance with drug therapy, decrease inconvenience for the patient and the provider, as well as decrease the quantity of controlled substances dispensed at one time. Prohibiting prescribers from issuing multiple prescriptions at one time will significantly impact patient access to these needed medications. Patients will be required to visit their physician for each new prescription – even if the patient has successfully been treated on the medication for some period of time. In most situations, patients will have to visit their physician or other prescriber on a monthly basis to

[2] 21 CFR Section 1306.05.
[3] Letter from G. Thomas Gitchel, DEA to Patrick Gavin, MEIJER, Inc. Dated June 8, 1995.
[4] Letter from Patricia Good, DEA to Howard Heit, physician. Dated January 31, 2003.

obtain a new prescription. Although prescribers could prescribe higher quantities of a medication to eliminate the need for frequent physician visits, the cost of a large supply may be cost prohibitive for cash paying patients and most insurance companies restrict patients to a 30-day medication supply. If patients are capable of securing the larger supplies of medications, it is unclear how introducing *higher* quantities of medications into patients' hands at one time is preferable to an approach that facilitates periodic patient/pharmacist interaction and the provision of smaller supplies and dispensed more frequently.

The need for frequent physician visits will decrease access for some patients. It will especially disadvantage the disabled, those in lower socioeconomic classes, those who may rely on other means for transportation, and those who are unable to travel. And while the Agency's interim policy statement is specific to controlled substance use in the treatment of pain, it is important to note that this change in policy will also affect all patients using controlled substances. For example, patients with attention-deficit hyperactivity disorder (ADHD) may be treated with a Schedule II controlled substance such as Ritalin® (methylphenidate). Once these individuals are stabilized on a medication, there may not be a specific medical reason for the patient to see a prescriber every thirty days; however, under the Agency's new interpretation of the CSA, ADHD patients would be required to see their physician monthly to obtain a new prescription. This will greatly inconvenience parents and caregivers who must take off time from work and, often, remove their children from school for monthly physician visits.

Prohibiting the issuance of multiple prescriptions at one time will also affect prescribers. While more frequent physician visits may produce higher incomes for prescribers (and higher health care costs for patients and insurance companies), it will also increase the prescriber's workload. It may be difficult for prescribers to see <u>every</u> patient on a Schedule II medication <u>every</u> month. Physicians may be hesitant to prescribe a Schedule II drug – even when medically necessary – when doing so will require the patient to visit the prescriber every month for a new prescription. This may have a chilling effect on health care providers' willingness to prescribe and dispense controlled substances.

The DEA's recent FAQ has led health care professionals to feel uncertain about their risk of investigation. This legitimate fear is further compounded by the fact that the DEA has reserved the right to "investigate merely on suspicion that the law is being violated, or even just because it wants assurances that it is not."[5] As it stands now, the Agency is sending the message to providers that they may be investigated for any reason or for no reason at all. This increased fear of DEA investigation and/or prosecution among the medical and pharmacy communities – even though the vast majority of prescribers and pharmacists are appropriate in their use of pain medications and other controlled substances – will have a "chilling effect" on the prescribing and dispensing of medically necessary controlled substances.

Education – Not Restricted Distribution – is the Answer

During a December 2001 U.S. House of Representatives Appropriations' Commerce, Justice, State, and Judiciary Subcommittee hearing on OxyContin®, both then-DEA Administrator Asa Hutchinson and Subcommittee Chairman Frank Wolf stated that they do not want or intend to restrict legitimate use of the drug. According to Hutchinson, the "DEA recognizes that the best means of preventing the diversion of controlled substances, including OxyContin® and all other drugs, is to increase awareness of the proper use and potential dangers of the products." The

[5] 69 FR at 67,171.

Association agrees, and notes that pharmacists can be an excellent communicator of that information.

APhA fully supports efforts to examine possible strategies to reduce the abuse and diversion of opiate analgesics without restricting access to drugs for patients with legitimate medical need. In October, 2001, APhA in collaboration with 20 other health care organizations and the DEA, released a joint consensus statement on the need to prevent abuse of prescription medications while ensuring that they remain available for patients in need. The groups recognized that for many patients, opiate analgesics are the only treatment option to provide effective and significant pain relief. However, a narrow focus on the abuse potential of a drug could erroneously lead to the conclusion that these medications should be avoided when medically indicated—generating a sense of fear rather than respect for their legitimate purpose.[6]

Striking a Balance

APhA generally supports the FDA's and the DEA's efforts to ensure that legitimate users of prescription medications maintain the ability to continue using these products, while reducing their diversion and abuse. However, we caution against efforts to restrict the distribution of certain medications or arbitrarily limit health care providers' ability to prescribe or dispense appropriate medications. With every barrier erected to limit diversion, the potential for those barriers to diminish appropriate prescribing increases exponentially. Restrictions in the drug distribution process can disrupt patient care by delaying access to medication therapy, disrupt existing patient-pharmacist-prescriber relationships, and potentially create an increase in the cost of medications. Also, any additional stigma attached to the drugs will have a significant chilling effect on health care providers' willingness to prescribe and dispense appropriate medication and patients' interest in using the medications. Decreasing the number of patients using a medication may be seen as a "success" in managing risk. But this "success" is tempered by the accompanying "failure" of patients with legitimate need to access the same medication.

Federal enforcement agencies, such as the DEA, should continue to be a law enforcement agency fighting the illegal diversion of drugs. But the DEA should not be turned into a medical oversight body – a task for which it is unsuited. Providing a government agency the explicit authority to question the intent of any physician or medical practitioner who authorized the use of a medication for a patient could increase doctors' reluctance to prescribe drugs resulting in more patients suffering, especially at the end of life. Drug therapy should be managed by healthcare professionals – physicians, nurses, and pharmacists – not by federal law enforcement officers. The very threat of regulatory intervention and oversight – and the fear of having their intentions misconstrued – could dissuade physicians from using aggressive efforts that are often needed to use medications effectively.

APhA encourages Congress to work with physicians, pharmacists, state and federal regulatory and law enforcement agencies, and representatives of pain management and other consumer organizations to examine possible strategies to reduce the abuse and diversion of controlled substances without decreasing patient access. It is imperative that the Agency strike an appropriate balance between providing adequate pain treatment and maintaining proper controls to prevent diversion and abuse. Despite assurances that the DEA's new policy statement does not

[6] A Joint Statement From 21 Health Organizations and the Drug Enforcement Administration. *"Promoting Pain Relief and Preventing Abuse of Pain Medications: A Critical Balancing Act."* Oct. 2001.

represent any change in the Agency's investigative emphasis or approach,[7] prescribers, pharmacists, and others perceive (appropriately) the Agency's withdrawal of support for the Prescription Pain Medications FAQ and the release of the interim policy statement as indicators that the DEA is placing a greater emphasis on investigation and prosecution. The chilling effect this perception will have on legitimate medical and pharmacy practice will be significant.

Thank you for your consideration of the views of the nation's pharmacists. APhA looks forward to working with the Committee to develop a safer and more effective system of providing prescription medications to all Americans.

[7] Letter from William Walker, DEA to William Winsley, Ohio State Board of Pharmacy. Dated January 27, 2005.